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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,276	11/26/2003	Gary R. Hollenbeck	11478-008-999	1253

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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	**PAPER NUMBER**
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/724,276	HOLLENBECK ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *18-20 and 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of response to Election/restriction requirement filed 3/7/07. Claims 1-22 are pending.

Election/Restrictions

1. Applicant's election of Group I, claims 1-17 and 21 in the reply filed on 3/7/07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 18-20 and 22 are withdrawn form consideration.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claims 1-17 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is written description.

Claims 1, 8 and 12 are directed to the use of polyelectrolyte in pharmaceutical compositions that contain drug-resin complex without identifying the ions associated with the polyelectrolyte. The specification does not describe the ions that may be associated with the polyelectrolyte. For example, Kupperblatt in US 5,882,677 at column 5, lines 34 and 35 disclose that polyelectrolyte having Hg or Ag ions would not be medically suitable. Therefore, the use of any polyelectrolyte without identifying the ions associated with the polyelectrolyte in the claimed composition would not lead the artisan away from using polyelectrolytes having associated Hg or Ag ions and as such the disclosure is insufficient to meet the requirements for adequate written description under 35 USC 112, first paragraph.

Applicant may overcome this rejection by incorporating claims 8 and/or 12 into claim 1 and at the same time show that the ions associated with these polyelectrolytes are not Hg or Ag without the introduction of new matter into the claims or disclosure.

Claim 21 recites condition or symptoms. The specification fails to describe those "conditions" and "symptoms" treatable by the claimed composition of claim 1. The specification is thus insufficient to meet the requirements of 35 USC 112, first paragraph, written description.

Applicant may overcome this rejection by reciting the specific symptoms or conditions without the introduction of new matter into the claims or disclosure.

5. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is dependent on claim 6. It is unclear which material in claim 7 corresponds to what material of claim 6.

Correction is respectfully requested.

Claim objection

6. Claim 7 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 7 recites "alginate, ...gelatin or combinations thereof," which do not appear to further limit the ion exchange matrix of claim 6.

Correction is respectfully requested.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-3, 5, 6, 8, 13, 14 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Cuna et al. ("Controlled-release liquid suspensions based on ion-exchange particles entrapped within acrylic microcapsule," in International Journal of Pharmaceutics 199 (2000), pp 151-158, provided by applicant on form PTO 1449).

Cuna discloses terbutaline-loaded ion-exchange resins where the resin is Dowex cation exchange resin of the H^+- form (abstract; paragraph 2.1-2.8) and EUDRAGIT polymer that meets the limitation of polyelectrolyte of claims 1 and 8; the dosage form contains hydroxypropylmethylcellulose meeting the limitations of claims 2 and 3 as the diffusion controlling membrane. Terbutaline is cation/positively charged in the resinate since the ion-exchange resin is a cation exchange resin. The presence of polysorbate meets the limitation of dispersion agent of claim 16 and the presence of the diffusible counter ions per liter of dispersion medium as claimed in claim 13 is inherent to the composition and the Dowex ion-exchange resin is a bead, thus meeting claim 14. Cuna anticipates the designated claims.

9. Claims 1-6, 13-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Chow et al. (US 4,859,461) or Sheumaker (US 4, 762,709) or Kogan et al. (US 5,186,930) or Kelleher et al. (US 4,996,047), all provided by applicant on form PTO 1449.

The references, Chow, Sheumaker, Kogan and Kalleher individually disclose drug ion-exchange complexes that contain diffusion barrier and that also contain dispersion medium, sweetening agent or flavoring agent and the ion-exchange resins are inherently beads or particles. The ion exchange resins of these references are cation exchange resins, based in styrene and divinyl benzene, such that the drugs are inherently positively charged. Counter ions are associated with the ion exchange resin and the claimed moles/liter of counter ions in the dispersion medium is inherent to the composition and the prior art meets that claim. Claim 17 is an inherent property of the dispersion agent.

See Chow (abstract; column 1, line 35 to column 3 line 14);

See Sheumaker (abstract; column 1, line 62 to column 4 line 44; claims 1-17);

See Kogan (abstract; column 2, line 13 to column 6 line 25).

Kelleher discloses drug-resin complex that is coated with water-permeable diffusion barrier (abstract); and the composition is a liquid oral dosage form (column 5, lines 65 and 66; column 6, lines 14-16); acidic drugs bind to anion-exchange resin and basic drug bind to cation exchange resin (column 4, line 55 to column 5 line 20); the diffusion coating barrier may contain natural or synthetic polymers such as ethylcellulose or methylcellulose, used singly or n admixture with each other, and in admixture with plasticizers, pigments (column 5, lines 34-53) meetings claims 15 and 16 and since the ion exchange resins, AMBERLITE is particle or beads, claim 14 is met; the mole/liter of counter ions present in the dispersion is a property of broad dosage forms that do not recite any specific amount of the ion-exchange resin so that the dosage from of the prior art inherently anticipates claim 13; the suspension of Example XIV contains xanthan gum, colorant, flavorant, polysorbate meeting claims 11, 12, 15 and 16; see also column 2, lines 9-68; column 6, lines 14-65 and Example XIV.

10. Claims 1-17 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Nonomura et al. (US 4,894,239) provided by applicant on form PTO 1449.

Nonomura discloses sustained release resin microcapsule preparation comprising ion-exchange resin (abstract), which dosage form is produced as oral suspension (column 4, lines 55-62) meet the requirement for liquid formulation; the ion-exchange resin is either cationic (H+ form) or anionic (OH- form) either as DOWEX or Amberlite (column 2, lines 16-23) meeting claim 14; the Dowex or Amberlite resins are of the styrene-divinyl benzene type resins meeting claims 6 and 10; when the ion exchange resin is cationic, the drug in the complex is positively charged meeting claim 5 and when the exchanger is anionic, the drug is negatively charged

meeting claim 9; the composition contains water permeable polymer coat formed of natural and non-natural polymers such as ethylcellulose, aminoalkyl methacrylate copolymer or the Eudragit polymer (column 3, lines 32-42) meeting claims 2-4; the composition or dosage form contains plasticizer or antioxidant such as BHA, BHT, tocopherol or tocopherol acetate (Column 4, lines 30-36) meeting claim 16 and the additive or antioxidant and or the wetting agents or surfactants or dispersing agents (column 4, line 66 to column 5 line 8) inherently meets the limitation of claims 16 and 17; the resinate is dispersed in Eudragit (column 7, lines 22-25) meeting the limitation of polyelectrolyte (claims 8 and 12); sucrose or fructose or sorbitol or lactose when present (column 4, lines 66, 67) meet claim 15; when gelatin or xanthan gum or guar gum (column 5, lines 4-7) meeting claims 6, 7, 11, 12; the mole/liter of counter ions present in the dispersion is a property of broad dosage forms that do not recite any specific amount of the ion-exchange resin so that the dosage from of the prior art inherently anticipates claim 13; the disclosure that the suspension is contemplated for oral administration (claim 12 and column 4, lines 55-57) meets the limitation of claim 21 since administration of any of the disclosed drugs would provide the effect of the drug that is obtainable from the drug.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-17 and 21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-29 of copending Application Nos. 11/150,937 (US 2006/0018972) and 11/198,937 (US 2006/0134148) in view of WO 95/19184. The copending claims differ from the examined claims in that the co-pending claims do not specify what the dispersing medium is comprised of. However, the Eudragit polymers are known as dispersing according to Cohen in WO 95/19184 (abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use Eudragit polymers as the dispersing polyelectrolyte in the dosage form of the examined claims.

This is a provisional obviousness-type double patenting rejection.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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